

claimed to be such in the continuing data inserted into the first page of the specification." A new Declaration has been prepared and will be submitted after the Applicants have executed the Declaration.

Claims 11-16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-7 in U.S. Patent No. 5,876,453. Claims 17-21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-4 in U.S. Patent No. 5,863,201. Claims 22-24 and 26 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 5-12 in U.S. Patent No. 5,863,201. Claims 27-50 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 5-7 in U.S. Patent No. 5,876,453. The Applicants will submit Terminal Disclaimers in compliance with 37 C.F.R. §§ 1.321 signed by an attorney of record, once the currently rejected claims have been indicated to be allowable.

As indicated in the Office Action, the Examiner has not reviewed the references submitted with Applicants' Information Disclosure Statement on March 29, 1999, "because it does not provide copies of all cited references which were not cited and provided in the parent applications." All of the references listed on Form PTO-1449 for the Information Disclosure Statement were

previously submitted by the Applicants or cited by the Examiner for parent Application Nos. 08/778,503, issued as U.S. Patent No. 5,863,201 on January 26, 1999, and 08/607,903, issued as U.S. Patent No. 5,876,453 on March 2, 1999. More specifically, A22, U.S. 5,344,457 (Pilliar) was cited by the Examiner in U.S. Application 08/778,503 and articles C1 (Albrektsson) and C3 (Bair) were included in the second Information Disclosure Statement in the same U.S. Application. (It appears that the Albrektsson article was indicated to be dated 1991, but should have been 1981.) Since it may be that the Patent and Trademark Office files do not have these three references, copies are enclosed for the Examiner's use. No fee is believed to be necessary, since the references are merely being resubmitted.

#### **§§ 102 and 103 Rejections**

Claims 11-16, 22-25 and 27-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,826,434 to Krueger ("Krueger") or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Krueger.

The Examiner contends that Krueger teaches a threaded product etched to remove impurities. He asserts that the product would have the native oxide layers removed and irregularities of less than 10 microns. In his patent, Krueger does not provide much detail regarding the methods used to etch the surface. He does say that, "Such etching will, . . . normally remove any surface

contamination or impurities on the surface 12 which might subsequently cause difficulty." (Column 3, lines 53-56). Also, he says that " . . . concentrated mineral acids are employed . . . ." (Column 4, line 1).

Krueger does not mention "native oxides" which are present on titanium surfaces. His reference to "surface contamination or impurities" suggests that he was referring to deposits left during the machining of titanium implants, rather than to native oxides, since they would not be characterized as contaminants or impurities. Thus, it cannot be concluded from the brief discussion that Krueger was aware that all of the native oxides should be removed before etching a titanium surface or how to do so. However, this is taught by the Applicants and illustrated in Examples 1 and 2, incorporated into the present application in the Second Preliminary Amendment, mailed March 17, 1999. In Example 1, titanium implants were blasted with titanium grit and thereafter the native oxide layer was removed by an aqueous solution of hydrogen fluoride. Then, the intermediate surface was etched with a mixture of sulfuric and hydrochloric acids. Example 2, illustrated the result when the hydrofluoric acid treatment was omitted. "[T]he bulk etch solution failed to remove the native oxide layer after 10 minutes in the etch solution. The failure to remove the native oxide layer resulted in a non-uniformly etched surface." Thus, the Applicants have shown that removal of the

native oxides is an important factor in achieving a uniformly etched titanium surface. This conclusion cannot be reached from the Krueger patent, either expressly or by implication. Consequently, the Applicants ask the Examiner to reconsider his rejections based on the Krueger patent.

The Examiner posits also that the surface irregularities of Krueger would be inherently the same as those in the present claims. This might be true if the etching solutions were the same and if the native oxide layer has been removed. But, as discussed above, and demonstrated in Example 2, unless the native oxide layer is removed, uniform etching does not result. Furthermore, claim 27, which requires only a peak to valley height of 0.3 to 10 microns, cannot be predicted from the minimal information supplied by Krueger.

The Examiner's comments with regard to claims 13 and 16 are not understood. These claims include preferred methods for carrying out the invention. The Examiner seems to say that the process steps are obvious because the resulting surface is obvious.

The term "smooth" is a term of relative degree, as the Examiner says, however, claim 36 is dependent from claim 27 in which the threaded portion is roughened to a defined degree. Thus, "smooth" should be understood to be relative to a defined degree of roughness. Krueger evidently intended his implant to be roughened throughout.

Claims 26 and 50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Krueger as applied to Claims 11-16, 22-25 and 27-49 and further in view of U.S. Patent No. 5,989,027 to Wagner et al. ("Wagner").

Krueger appears to have intended to roughen by etching his entire implant (surface 12 in Figure 3). Wagner has been cited for the use of different regions of roughness. However, Wagner does not teach selective etching of a portion of the threads, as the Applicants do, or complete etching as Krueger teaches. It is inconsistent to contend that the selective roughness of Wagner could be applied to the contrary teachings of Krueger. Also, it is noted that the Applicants' teachings find support in the earliest application, predating the PCT filing date of Wagner.

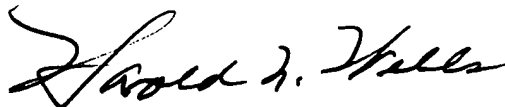
#### **Conclusion**

It is the Applicants' belief that all of the claims are now in condition for allowance, and action towards that effect is respectfully requested.

If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney at the number indicated.

Respectfully submitted,

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